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Case Docket No. 1171/38910/79

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Cheryl K. Jarot
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Transmitted herewith for filing is the patent application of

Inventor: CRAIG ROBERT JEFFREY
GRAEME WOOLMORE
ANTHONY JAMES NEWLAND

For: **Breathing Assistance Apparatus**

Enclosed are:

☒ Four (4) informal sheets of drawings.

☒ An unexecuted Declaration and Power of Attorney for Patent Application.

The filing fee has been calculated as shown below:

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- ☒ Any filing fees required under 37 CFR 1.16 for the presentation of extra claims.

Dated: September 8, 2000

Linda L. Palomar Reg. No. 37,903
Attorney of Record

BREATHING ASSISTANCE APPARATUS

BACKGROUND TO THE INVENTION

i) Field of the Invention

The present invention relates to the use of a pressure regulator in conjunction with a breathing assistance apparatus, particularly though not solely, for regulating the pressure of gases supplied to a patient from a humidified Positive End Expiratory Pressure (PEEP) apparatus.

ii) Summary of the Prior Art

The use of a medical apparatus to facilitate breathing is well known in the art. The apparatus may take the form of a simple oxygen mask or tent which supplies oxygen at slightly above atmospheric pressure. Such devices merely assist a person to breath and work with the person's lungs.

Ventilators which operate at high frequency have been suggested in the past. There are two types of high frequency ventilators known in the art. One type, as exemplified by US Pat. No. 2,918,917 (Emerson), employs a reciprocating diaphragm to vibrate a column of gas supplied to a subject. The vibration is in addition to the subject's respiration, natural or artificial, and at a much more rapid rate, for example, from 100 to more than 1500 vibrations per minute. The Emerson apparatus is primarily designed to vibrate the patient's airway and organs associated therewith, although Emerson also recognized that high frequency vibration causes the gas to diffuse more rapidly within the airway and therefore aids the breathing function. However, the Emerson apparatus is incapable of supporting the patient's full ventilation and must be used in conjunction with the patient's spontaneous breathing or with another apparatus which produces artificially induced inhalation and exhalation.

The second type of high frequency ventilator is the jet pulse ventilator as exemplified in US Patent No. 4,265,237 (Schwanbom et al.). The Schwanbom et al. ventilator produces high frequency, high pressure pulses of air which are capable of fully ventilating a patient. The respiration pulse enters with a pressure of 0.2 bar to 2.7 bar. This pressure is sufficient to expand the lungs during inspiration. Expiration is caused by the natural compliance of the lungs after the jet of air is stopped. Accordingly, it can be seen that Schwanbom et al must rely on the compliance of the lungs in order to fully ventilate the patient. If the lung compliance is low, greater pressure must be used. Schwanbom et al also supply a source of lower pressure gas for spontaneous breathing by the patient. While such jet pulse ventilators are useful for some applications, they are not generally applicable and their use is limited mostly to

experimental work.

An improvement on these types is disclosed in US Patent No. 4,821,709 (Jensen) a which provides high frequency oscillations in the gases supplied to a patient using a flexible diaphragm. Jensen provides a more practical method of ventilating a patient without spontaneous breathing of the patient, or the need for a separate ventilator. US Patent No. 4,646,733 (Strot et al.) proposes an apparatus for producing high frequency oscillations in gases supplied to a patient using a valve controlling the exhaled gases.

It would be desirable to have a simple system for providing high frequency pressure oscillations for spontaneously breathing patients particularly for non invasive forms of support, where the means level of gases provided to the patient can be adjusted.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a pressure regulator which goes some way to overcoming the above-mentioned disadvantages, or which will at least provide the healthcare industry with a useful choice.

Accordingly, in a first aspect, the present invention consists in a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid,

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to a breathing assistance apparatus and in use accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the mean pressure of said inhalatory gases supplied to a patient is adjusted by the level to which said distal end is submerged in said body of liquid.

In a second aspect, the present invention consists in a breathing assistance apparatus for supplying gases to a patient to assist said patient's breathing including: gases supply means adapted to supply gases to said patient, delivery means including a plurality of ports adapted to deliver said flow of gases to said patient, inhalatory gases transport means for conveying said flow of gases from said gases supply means to said delivery means, exhalatory gases transport means for conveying said patient's exhalations from said delivery means, and a pressure regulating device disposed within or in fluid communication with said exhalatory gases transport means, said pressure regulating device comprising:

a container which in use includes a body of liquid, and

terminal conduit means including proximate and distal ends, said proximate end in use

connected to said exhalatory gases transport means and accepting said patient's exhalations therefrom, and said distal end submerged in said body of liquid,

such that in use the mean pressure of said inhalatory gases supplied to said patient is adjusted by the level to which said distal end is submerged in said body of liquid.

In a third aspect, the present invention consists in a pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid, and

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to a breathing assistance apparatus and accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the resultant bubbling occurring in said body of water produces relatively small controlled perturbations in the pressure of inhalatory gases supplied to a patient.

To those skilled in the art to which the invention relates, many changes in construction and widely differing embodiments and applications of the invention will suggest themselves without departing from the scope of the invention as defined in the appended claims. The disclosures and the descriptions herein are purely illustrative and are not intended to be in any sense limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block diagram showing a typical configuration for supplying breathing assistance to a patient,

Figure 2 is a plan view of the pressure regulator with the lid on according to the preferred embodiment of the present invention,

Figure 3 is a side view of the pressure regulator according to the preferred embodiment of the present invention,

Figure 4 is a cross-section of the pressure regulator according to the preferred embodiment of the present invention,

Figure 5 is an alternative side view of the pressure regulator according to the preferred embodiment of the present invention,

Figure 6 is a perspective view of the short conduit which extends into the water chamber according to the preferred embodiment of the present invention,

Figure 7 is a cross-section of the complete pressure regulator according to the preferred

embodiment of the present invention, and

Figure 8 is a cross-section of a further embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a means of producing the variations or oscillations in the pressure of gases supplied to a patient connected to a positive pressure ventilation device. By submerging the end of the exhalatory conduit into a water column the resulting bubbles generate a variation or ripple in the mean pressure of gases delivered to the patient. In doing so it also provides a simple method of varying the mean pressure of gases supplied to the patient by variation of the level to which the end of the exhalatory conduit is submerged within the water column. In order to keep the mean pressure of gases supplied to the patient constant the level of submergence of the end of the exhalatory conduit must be kept constant and an apparatus for ensuring this occurs is also disclosed.

Referring now to Figure 1 in which a typical application is depicted. A humidified Positive End Expiratory Pressure (PEEP) system is shown in which a patient 119 is receiving humidified and pressurised gases through a nasal mask 128 connected to a inhalatory conduit 121. It should be understood that the present invention, however, is not limited to the delivery of PEEP gases but is also applicable to other types of gases delivery systems and may not necessarily involve humidification. Inhalatory conduit 121 is connected to the outlet 112 of a humidification chamber 110 which contains a volume of water 115. Inspiratory conduit 121 may contain heating means or heater wires 118 which heat the walls of the conduit to ensure a constant humidity profile along the conduit and therefore reduce condensation of humidified gases within the conduit. As the volume of water 115 within humidification chamber 110 is heated, water vapour begins to fill the volume of the chamber above the water's surface and is passed out of the humidification chamber 110 outlet 112 with the flow of gases (for example air) provided from a gases supply means or blower 118 which enters the chamber 110 through inlet 116.

The humidified gases pass through the inhalatory conduit 121 to the mask 128 attached around the patient's 119 mouth. The excess gases then flow through the exhalatory conduit 130 to a pressure regulator 134.

Pressure Regulator

In the preferred embodiment of the present invention the pressure regulator 134, takes the form of discharging the flow of exhalatory gases into a chamber 204 containing a column of water 138. The gases flowing through the exhalatory conduit 130 are discharged into the

body of water 138 from a short conduit 136 which extends from the expiratory conduit into the chamber 204. This results in a bubbling effect, whereby the gases eventually exit the chamber 204 via the outlet port 152, which can also be used to initially fill the chamber 204 with water. The outlet port 152 includes shielding to prevents liquid aerosols created by the vigorous bubbling on the surface of the water from being expelled. It will be appreciated that the short conduit 136, could equally be integrated into the end of the expiratory conduit 130.

Referring now to Figures 2 through to 7, the pressure regulator 134 and associated components are seen in more detail. The exhalatory conduit (130, Figure 1) fits into the end of the short conduit 136 which in turn is attached to the lid 144 of the water chamber 142 via connector 146. The connector 146 includes a number of resilient ridges or plastic toggles 148 which lock into annular grooves 150 in the short conduit 136 to keep it locked in a desired position during use. The chamber 204 is filled with a body of water 138 up to a predetermined lever 140. It will be appreciated that any appropriate liquid could be used instead of water.

It will be appreciated that for control over the mean pressure of supplied gases it is necessary to vary the level of which the short conduit 136 is submerged in the body of water 138. Stepped variations in the pressure of gases delivered to the patient of ½ cm H_2O each, are thought adequate for most applications, and is achieved by spacing each of the annular grooves 150 ½ cm apart. A contoured gripping portion 147 is provided at the end of the short conduit 136 which attaches to the exhalatory conduit 130, to allow easy adjustment. In one embodiment, the pressure is adjustable over a range from 4-8 cm H_2O but it will be appreciated that this can be modified to requirements. The pressure regulator according to the preferred embodiment of the present invention is shown in Figure 7, adjusted to its highest pressure setting. The settings could be indicated by a number above each groove 150 on the short conduit 136, which would be visible above the connector 146.

Constant Water Level

In the preferred embodiment, the present invention is used in conjunction with a humidified PEEP respirator. As such, the exhalatory gases will have quite high levels of humidity, some at which will inevitably condense in the body of water 138 in the pressure regulator 134. Thus, over time the volume of water in the water chamber 204 will rise and if unchecked will result in rising pressure of gases supplied to the patient and resultant adverse side effects. To ensure the water level is kept constant the water chamber 204 is provided with an overflow facility 218 also seen in Figures 2 to 7.

Because of the vigorous bubbling occurring at the top of the body of water a simple lip over which excess liquid can flow would be ineffective and therefore some form of filtering

or damping is required. In order to mitigate the effect of the vigorous bubbling near the top of the chamber 200 a main outlet port 202 from the main chamber 204 is provided at a substantially lower level than where the bubbles would normally be expected to occur. However, the bubbling also causes pressure waves throughout the body of the liquid. These pressure waves would normally be reflected through the main outlet port 202 into the levelling chamber 206 and therefore result in more water escaping than it is desired. To alleviate the effect of the pressure waves a wave shield 208 is located in an intermediate position between the upper level of the water 210 and the main outlet port 202. This masks the outlet port 202 from the majority of the pressure waves due to the surface bubbling.

This effectively means that the water level in the levelling chamber 206 is relatively calm and substantially representative of the mean (as opposed to the instantaneous) water level in the main chamber 204. The water level in the intermediate overflow chamber 206 in turn is regulated by an overflow port 212 situated on a raised adjacent platform 214. The overflow port 212 is surrounded by a slightly cylindrical raised partition 216 in order to overcome the effect of any small remaining waves in the intermediate overflow chamber 206.

The water then flows into the detachable overflow container 218 which when full may be detached in use and emptied. Both the main chamber 204 and the intermediate overflow chamber 206 are integrally injection moulded using a clear plastic. The separate overflow container 218, is also injection moulded using a clear plastic as is the separate short conduit 136.

Further Embodiments

It will also be appreciated that the apparatus used to vary the mean water level in the main chamber may take a number of forms. While in the preferred embodiment a slidable conduit is used, other forms such a concertina baffle or rotatable conduit, for example, would be equally applicable. It will also be appreciated further forms of the overflow facility will be possible. For example the further embodiment shown in Figure 8, uses a thin slot 162 to pass water into a second chamber 160, where baffles smooth any variations before the overflow opening 166 into the overflow chamber 168.

Advantages

- Allows easy adjustment of the mean pressure level.
- Allows high frequency pressure oscillations for spontaneously breathing patients.
- Maintains constant mean pressure with low or no maintenance.
- Disposable and cheap compared with prior art ventilators.

WHAT WE CLAIM IS:

1. A pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid,

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to a breathing assistance apparatus and in use accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the mean pressure of said inhalatory gases supplied to a patient is adjusted by the level to which said distal end is submerged in said body of water.

2. A pressure regulating device as claimed in claim 1, further comprising a connection means attached to said container and engaging said terminal conduit means, whereby in use said terminal conduit means may be adjusted in axial position in predetermined increments, with respect to said connection means.

3. A pressure regulating device as claimed in claim 2 wherein said terminal conduit means includes at least one partial groove and said connection means includes at least one matching partial resilient ridge or toggle.

4. A pressure regulating device as claimed in either of claims 2 or 3 wherein said predetermined increments are one half centimetre each.

5. A pressure regulating device as claimed in claims 1 or 2 further comprising overflow means for regulating the level of said body of liquid with respect to said container to a substantially constant level.

6. A pressure regulating device as claimed in claim 5 wherein said overflow means also includes damping means for filtering any perturbations in said level of said body of liquid, such that in use said overflow means regulates the "mean" level of said body of liquid.

7. A pressure regulating device as claimed in claim 6 wherein said damping means comprises an outlet from said container which is located at a position which in use is substantially below the level of said body of liquid, and means for reducing the pressure waves

at said outlet produced in use in said body of liquid by patient's exhalations flowing therethrough located at a position which in use is between the level of said body of liquid and said outlet.

8. A pressure regulating device as claimed in any one of claims 5 to 7 wherein said overflow means further includes a removable container, whereby in use the overflow from said body of liquid flows into said removable container.

9. A pressure regulating device as claimed in claim 8 wherein said body of liquid is substantially composed of water.

10. A pressure regulating device as claimed in claim 9 wherein said device is constructed substantially from clear plastic materials.

11. A breathing assistance apparatus for supplying gases to a patient to assist said patient's breathing including gases supply means adapted to supply gases to said patient, delivery means including a plurality of ports adapted to deliver said flow of gases to said patient, inhalatory gases transport means for conveying said flow of gases from said gases supply means to said delivery means, exhalatory gases transport means for conveying said patient exhalations from said delivery means, and a pressure regulating device disposed within or in fluid communication with said exhalatory gases transport means, wherein said pressure regulating device comprises a pressure regulating device as claimed in any one of claims 1 to 10.

12. A breathing assistance apparatus as claimed in claim 11 further comprising humidification means for humidifying said gases prior to delivery to said patient, disposed within or in fluid communication with said inhalatory gases transport means.

13. A pressure regulating device for use with a breathing assistance apparatus which conveys inhalatory gases to, and removes exhalatory gases from a patient requiring breathing assistance, comprising:

a container which in use includes a body of liquid, and

terminal conduit means including proximate and distal ends, said proximate end adapted for connection to breathing assistance apparatus and accepting exhalatory gases therefrom, and said distal end submerged in said body of liquid,

such that in use the resultant bubbling occurring in said body of liquid produces relatively small controlled perturbations in the pressure of inhalatory gases supplied to a patient.

ABSTRACT

A pressure regulator is disclosed for regulating the expiratory flow in a CPAP system. The regulator comprises submerging a tube into a column of water. Improvements are included for adjusting the level to which the tube is submerged and for ensuring constant water level.

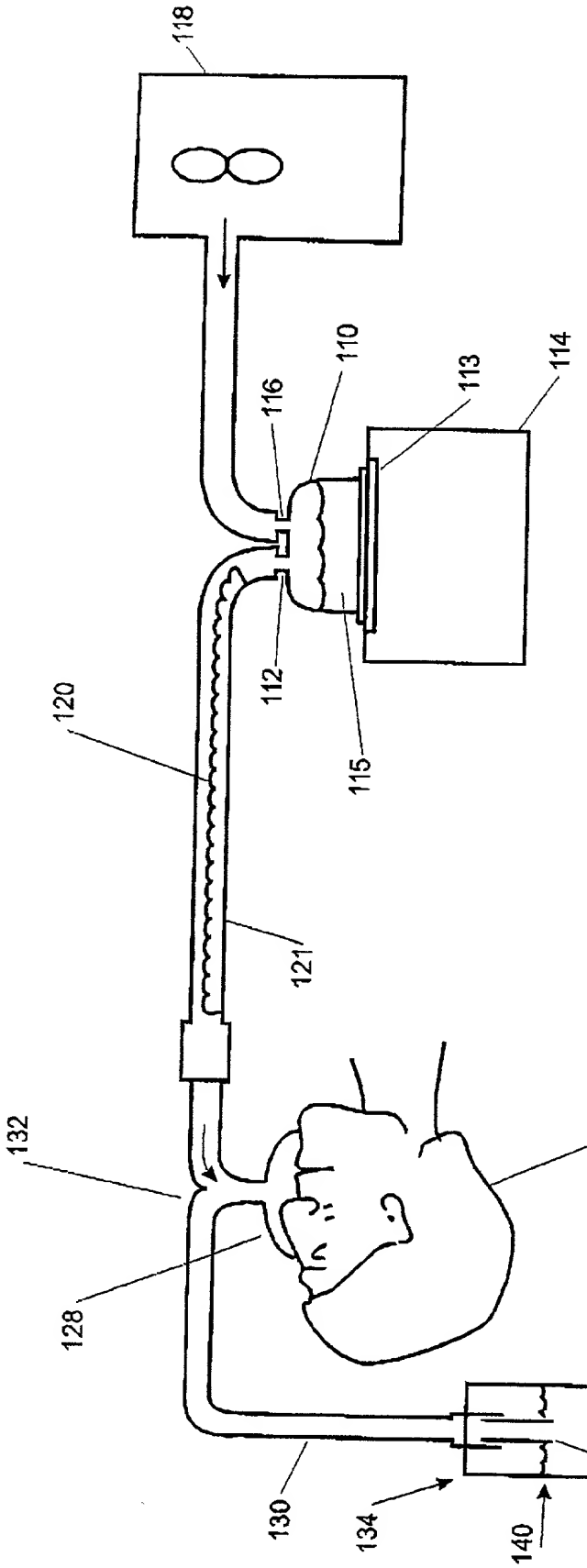
118
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FIGURE 1

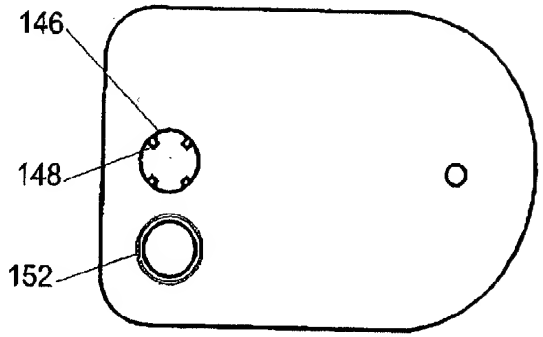


FIGURE 2

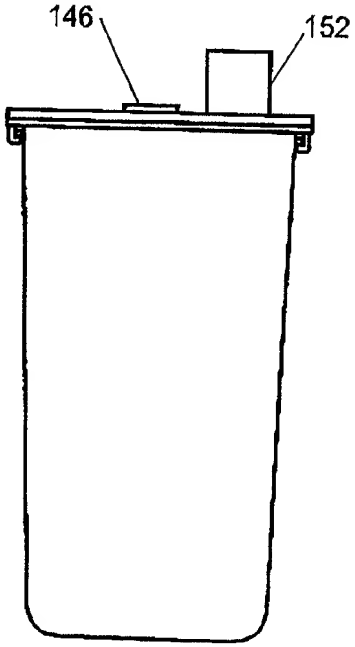
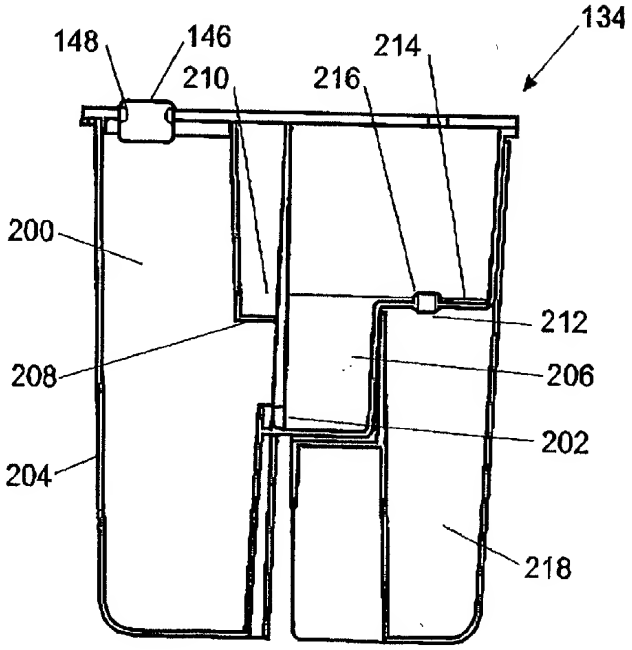


FIGURE 3



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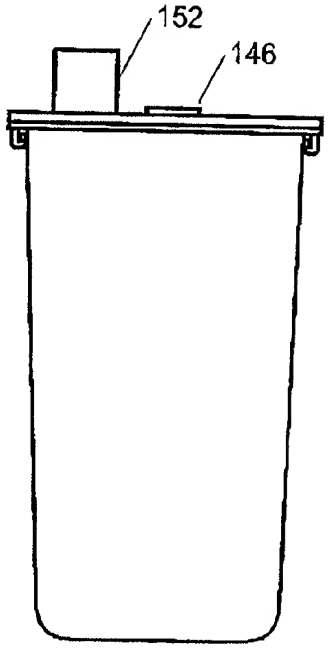

FIGURE 5

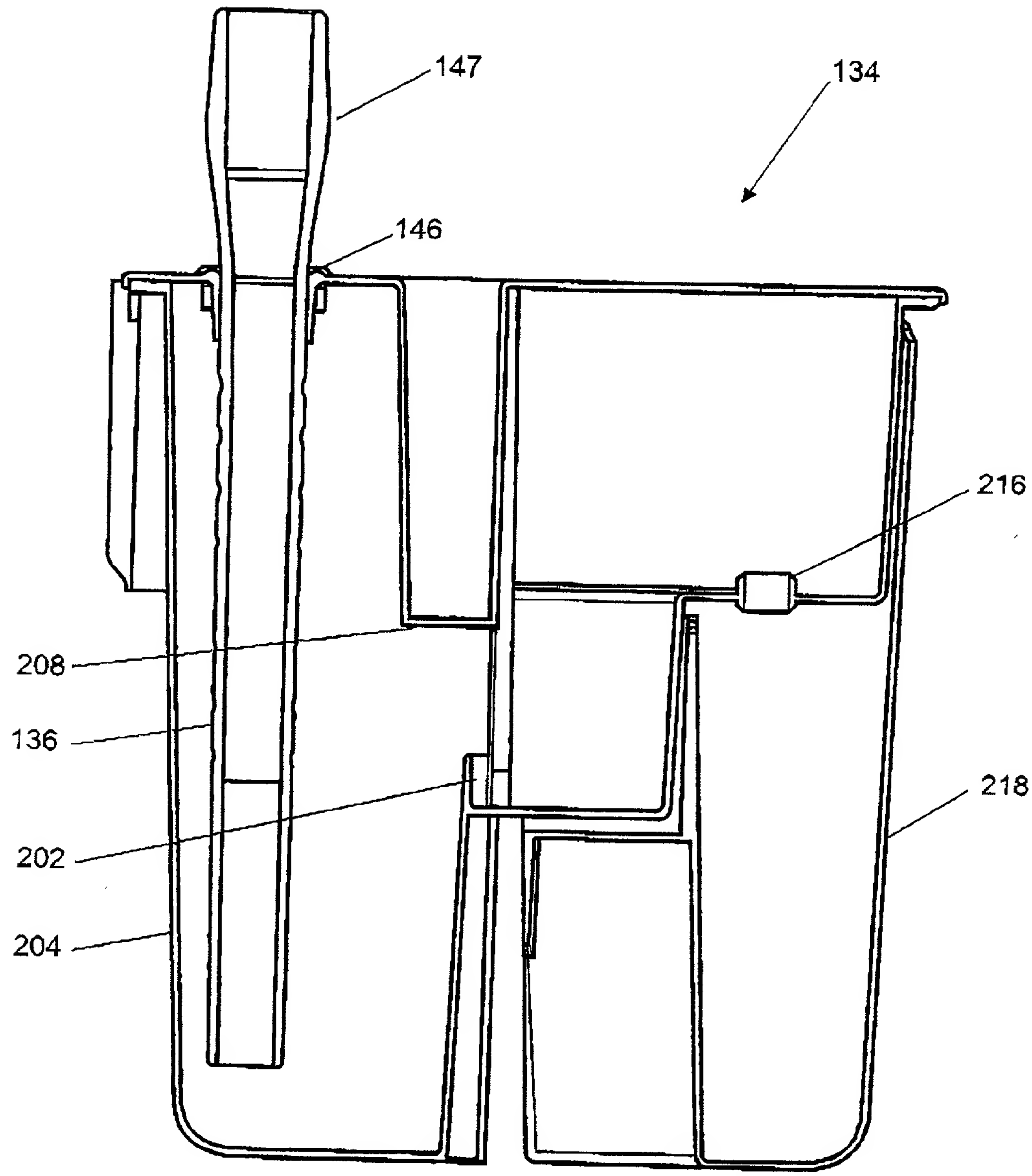

FIGURE 7

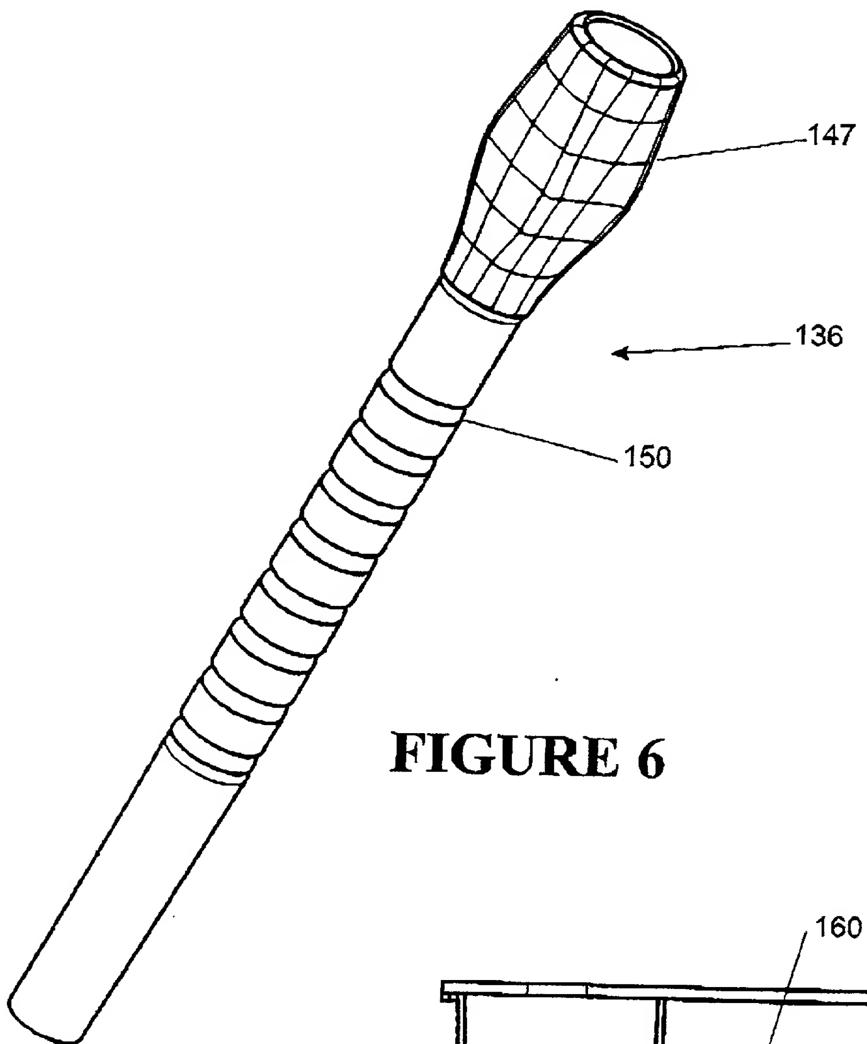

FIGURE 6

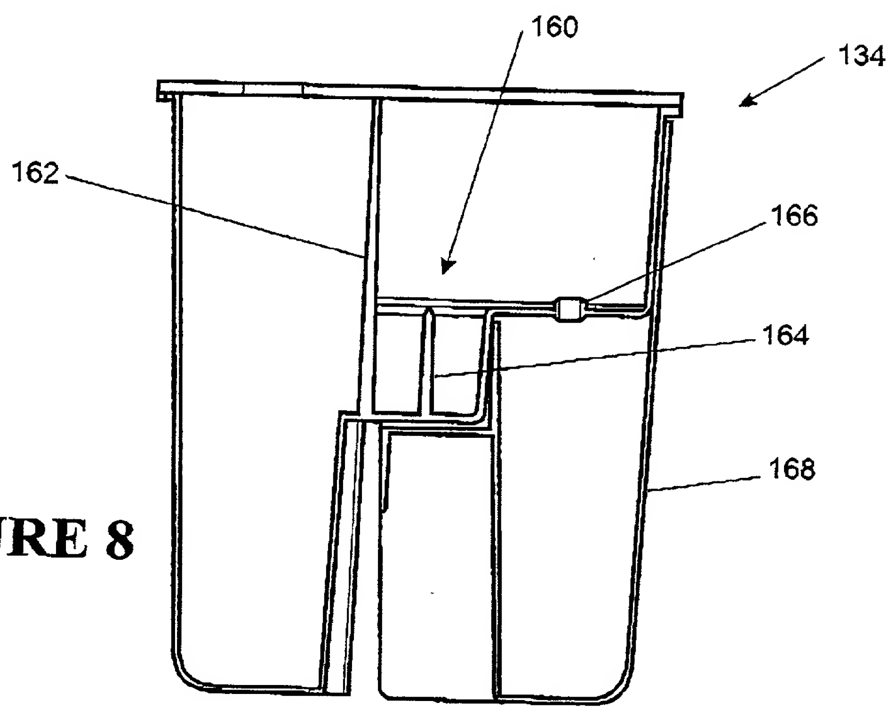

FIGURE 8

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name,

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: **BREATHING ASSISTANCE APPARATUS**, the specification of which

(check one) [X] is attached hereto.
[ ] was filed on _____ as
Application Serial No. _____
and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
337950 (Number)	New Zealand (Country)	20 September 1999 (Day/Month/Year Filed)	[X] Yes	[ ] No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	[ ] Yes	[ ] No
_____ (Number)	_____ (Country)	_____ (Day/Month/Year Filed)	[ ] Yes	[ ] No

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below; insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status: patented, pending, abandoned)
_____ (Application Serial No.)	_____ (Filing Date)	_____ (Status: patented, pending, abandoned)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952 and Paige A. Kitzinger, Reg. 45,219.

SEND CORRESPONDENCE TO: TREXLER, BUSHNELL, GIANGIORGI & BLACKSTONE, LTD.
105 W. ADAMS STREET, CHICAGO, IL 60603

DIRECT TELEPHONE CALLS TO: (312) 704-1890 RAIFORD A. BLACKSTONE, JR.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor **CRAIG ROBERT JEFFREY**

Inventor's signature _____ Date _____

Residence Auckland, New Zealand
Citizenship New Zealand
Post Office Address 373 East Coast Road, Mairangi Bay, Auckland, New Zealand

(Supply similar information and signature for second and subsequent joint inventors.)

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

Richard A. Giangiorgi, Reg. 24,284; Raiford A. Blackstone, Jr., Reg. 25,156; David J. Marr, Reg. 32,915; Linda L. Palomar, Reg. No. 37,903; James R. Foley, Reg. 39,979; James A. O'Malley, Reg. 45,952 and Paige A. Kitzinger, Reg. 45,219.

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Full name of second inventor **GRAEME WOOLMORE**

Inventor's signature _____ Date _____

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Citizenship New Zealand
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Full name of third inventor **ANTHONY JAMES NEWLAND**

Inventor's signature _____ Date _____

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Post Office Address 1/163 Riddell Road, Glendowie, Auckland, New Zealand